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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,208	10/02/2003	Scott Cunningham	2874	9627

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Tyco Healthcare Group LP
60 MIDDLETOWN AVENUE
NORTH HAVEN, CT 06473

EXAMINER	
HOLLM, JONATHAN A	

ART UNIT	PAPER NUMBER
3734	

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05/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,208	CUNNINGHAM, SCOTT	
	Examiner	Art Unit	
	JONATHAN A. HOLLM	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,10,11,13,14,16-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,10,11,13,14,16-20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed 22 February 2010 has been entered. **Claims 2-3, 10-11, 13-14, 16-20, and 22-25**. Response to applicant's arguments can be found at the end of this office action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 2-3, 10-11, 20, and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US Patent Number 4,513,747) in view of Silverman (US Patent Number 5,464,422) and Cottrill (US Patent Number 20,409) and Allen (US Patent Number 5,403,344).

Smith discloses a surgical needle comprising an elongate needle body defining a longitudinal axis and including a main shaft (41), a needle end adjacent the main shaft and including a first distinct set of intersecting surfaces (31, 32), a needle tip extending from the needle end and having an extreme needle point and including a second distinct set of intersecting surfaces (34, 35) that intersect the first set of surfaces to form edges (51, 52) at each line of intersection of the first and second sets that are capable of cutting (See figures 1-3); wherein the surfaces are arranged obliquely arranged relative

to the longitudinal axis with the second set of surfaces arranged at a greater angle than the first set of surfaces; the main shaft being curved.

The device of Smith is not explicitly disclosed with the first and second sets having four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section and means for attaching a suture. Silverman et al teach a needle having four sides symmetrically arranged about a longitudinal axis to form a diamond cross-section and including means for attaching a suture (see figures 1A-1C; column 2, lines 38-39). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Smith to have the first and second sets have four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section and include means for attaching a suture in view of Silverman et al in order to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue and allows for the needle to be used in a suturing procedure close a wound in the tissue.

The modified device of Smith in view of Silverman et al is not explicitly disclosed with the first and second sets being generally concave. Cottrill teaches having concave surfaces in a needle (see figures 1-2). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Smith in view of Silverman et al to have the surfaces of the first and second set be concave in view of Cottrill, since Cottrill teaches that such a configuration provides for better cutting edges and allows for less force required for penetration.

The modified device of Smith in view of Silverman et al and Cottrill is not explicitly disclosed with the needle end having a maximum cross-section dimension greater than a maximum cross-sectional dimension of the main shaft. Allen teaches a needle end defining a maximum cross-sectional dimension being greater than a maximum cross-sectional dimension of the main shaft (See figures 2-3). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Smith in view of Silverman et al and Cottrill to have the needle end have a maximum cross-section dimension greater than a maximum cross-sectional dimension of the main shaft in view of Allen in order to facilitate insertion of the main body of the suturing needle into a target site to suture the target site.

4. **Claims 13-14, 16-19, and 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US Patent Number 4,513,747) in view of Silverman (US Patent Number 5,464,422) and Cottrill (US Patent Number 20,409).

Smith discloses a surgical needle comprising an elongate needle body defining a longitudinal axis and including a main shaft (41), a first distinct set of intersecting surfaces (31, 32), a second distinct set of intersecting surfaces (34, 35) that are contiguous with the first set of surfaces, that extend to an extreme needle point, and that intersect the first set of surfaces to form edges (51, 52) at each line of intersection of the first and second sets that are capable of cutting (see figure 1); wherein the surfaces are arranged obliquely arranged relative to the longitudinal axis with the second set of surfaces arranged at a greater angle than the first set of surfaces (see

figure 3) and cutting edges are defined at the intersection of adjacent surfaces of the first and second sets.

The device of Smith is not explicitly disclosed with the first and second sets having at least three surfaces. Silverman et al teach a needle having at least three surfaces (see figures 1A-1C). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Smith to have the first and second sets have at least three surfaces in view of Silverman et al in order to provide more cutting edges for more efficient cutting and penetration of tissue.

The modified device of Smith in view of Silverman et al is not explicitly disclosed with the first and second sets being non-linear. Cottrill teaches having non-linear, concave surfaces in a needle (see figures 1-2). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Smith in view of Silverman et al to have the surfaces of the first and second set be non-linear and concave in view of Cottrill, since Cottrill teaches that such a configuration provides for better cutting edges and allows for less force required for penetration.

Regarding **claims 16-17**, Silverman discloses the surfaces of the needle being four in number (see figures 1A-1C).

Regarding **claims 24-25**, Silverman discloses the surfaces of the needle being symmetrically arranged about the longitudinal axis (see figures 1A-1C).

Response to Arguments

5. Applicant's arguments filed 22 February 2010 have been fully considered but they are not persuasive.

6. Regarding Applicant's arguments regarding Smith (US Patent 4,513,747), the Examiner reiterates that the edges (51, 52) are capable of cutting. The edges (51, 52) are formed along each line intersection of the first (31, 32) and second (34, 35) sets of surfaces and formed with angles similar to those of other cutting edges of the needle (column 5, lines 1-42), and would therefore be capable of cutting. Smith also discloses this configuration adds cutting edges to a needle and resists burring when the needle is used in hard tissue (column 5, lines 54-60). Further, Applicant has not provided any evidence that the edges (51, 52) are not capable of cutting.

7. In response to applicant's arguments against the Smith individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As cutting edges are provided around the circumference of the needle by the combination of Smith and Silverman, there is no intervening extended surface without cutting edges, as alleged by Applicant.

8. Regarding Applicant's arguments concerning the Silverman (US 5,464,422) reference, the teaching relied upon in the Silverman reference is that of providing a needle with four surfaces symmetrically arranged about the needle's longitudinal axis. Even though Silverman discloses a tip portion different from that disclosed by Smith,

one of ordinary skill in the art would have recognized the provision of four symmetrical surfaces to a set of surfaces on the needle as improving the cutting design of a needle. As such, one of ordinary skill in the art would have found it obvious to modify the device of the device of Smith by providing each set of surfaces with four surfaces, as taught by Silverman, to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN A. HOLLM whose telephone number is (571) 270-7529. The examiner can normally be reached on Monday - Friday 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAH/

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734